



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/645,892

08/20/2003

Michael C. Bednarek

11531US.01

8201

33486 7590 05/03/2010
HEIMBECHER & ASSOC., LLC
P O BOX 33
HAMEL, MN 55340-0033

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

05/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/645,892	Applicant(s) BEDNAREK, MICHAEL C.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-16 and 18-33 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 27-31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 is/are allowed.
- 6) ☒ Claim(s) 3-16, 18-24, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 Aug 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received April 5, 2010, have been fully considered by the examiner. Claims 25 and 27-31 remain withdrawn from consideration. The following is a complete response to the April 5, 2010 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 3-16, 18 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al (6,837,886).

Collins et al disclose an ablation catheter comprising a fixed braided electrode (28) for forming an ablation lesion. As shown in Figure 20E, the ablation electrode is encapsulated (i.e. between inner and outer walls) in a shroud (137). A plurality of openings (139) are provided to allow the exposed portions of the braided electrode to come into contact with tissue (col. 14, lines 25-33). Collins et al also disclose providing a fluid through the braided electrode member (col. 13, lines 65-67) by directing the irrigant with the shroud member. Collins et al disclose the use of a conductive irrigant, and the Collins et al device is deemed to operate to treat tissue in the same manner (e.g. ohmic heating, convection, conduction, etc.) as recited in applicant's claims. The only feature not expressly shown by Collins et al is the provision of an inner wall in the embodiment of Figure 20E.

However, Collins et al do clearly teach that it is known to provide the shroud-embodiments of Figures 20A-20E with inner and outer tubular structures between which

Art Unit: 3739

the braided member is located. With reference to Figure 20B, Collins et al specifically teach that it is advantageous to provide an internal shroud (134) with the braided electrode being provided between the inner and outer shrouds (col. 14, lines 7-12). Hence, Collins et al clearly teach it is known to provide a “sandwiched” braided electrode assembly. The examiner maintains that the use of such an internal shroud in the embodiment of Figure 20E would be an obvious design consideration for the skilled artisan.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al ('886) in further view of the teaching of Bednarek et al (6,120,500).

Collins et al fail to disclose a second lumen for carrying a control wire for shaping the catheter body as recited in these claims.

As addressed in the previous Office action, Bednarek et al discloses another ablation catheter that provides a second lumen (23 - Figure 11) including a control wire (16) for providing a pre-curved shape to the catheter body (Figure 2).

To have provided the Collins et al catheter device with a second lumen for housing a control wire to control the shape of the catheter would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Bednarek et al.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al ('886) in view of the teaching of Bednarek (6,120,500) as applied to claim 23 above, and further in view of the teaching of Swartz et al (6,080,151).

The combination of the Bednarek et al teaching with the Collins et al device has been addressed. While each of these catheters provide a wire connected to the electrode means, there is no express disclosure that the wire is carried through the second lumen (i.e. isolated from the fluid lumen).

The examiner maintains that the passage of wires through various lumens is generally known in the art, and that to have provided the Collins et al wire through either lumen (after considering the modification suggested by Bednarek et al) would have been an obvious design consideration. However, Swartz et al is cited as showing that it is generally known to provide electrode leads through a second lumen to keep the wires separate from the fluid delivery lumen. See, for example, Figure 3.

To have provided the Collins et al device, as modified by the teaching of Bednarek et al, with the lead extending through the second lumen to isolate the wire from the fluid lumen would have been an obvious design modification for one of ordinary skill in the art in view of the teaching of Swartz et al.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker et al (5,643,197) in view of the teachings of Collins et al ('886) and Levin et al ('830).

Brucker et al disclose an ablation catheter comprising a catheter shaft (22) defining an inner tubular structure and an outer tubular structure, a braided electrode (91) wherein the radius from any point of the braided electrode to a central axis of the inner tubular structure is constant (see Figure 16). Brucker et al fail to disclose the braided electrode being located between the inner and outer surfaces. Rather, the

Art Unit: 3739

Brucker electrode is recessed within the outer surface. Brucker et al also fail to disclose a raised surface for the braided electrode.

The Collins et al device has been addressed previously. Collins et al clearly disclose a braided electrode member embedded in the wall of a catheter (i.e. shroud) such that the electrode is between inner and outer walls (Figure 20B). Collins et al also fail to disclose the electrode defines a surface that is raised above the outer surface of the catheter shaft.

As addressed in previous Office actions, Levin et al disclose a catheter having an electrode embedded in the wall of a catheter. In particular, Levin et al teach that it is known to provide the electrode with a surface that is raised above the outer surface of the catheter shaft to facilitate placement against tissue.

To have formed the Brucker et al device, as modified by the teaching of Collins et al, with an electrode that projects slightly from the outer wall of the catheter to facilitate contact with tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Levin et al.

Response to Arguments

Regarding claim 26, applicant's arguments are deemed persuasive and the rejection has been withdrawn. Claim 26 is deemed allowable over the prior art of record.

Regarding claim 33, applicant's arguments are not persuasive. Applicant argues on page 8 of the April 5, 2010 response that Collins teaches a braided electrode anchored at respective ends of the tubular structure. However, this disclosure is

Art Unit: 3739

directed to an entirely different embodiment than the one referenced in the rejection above. The rejection above, which is substantially identical to the rejection proffered in the January 11, 2010 Office action, clearly relies on Figures 20A-20E in support of the rejection. Figure 20B clearly shows an embodiment where the braided electrode is provided between inner and outer shrouds (col. 14, lines 7-12). As such, the examiner maintains the rejection of claim 33 and its dependent claims.

Regarding claim 32, the examiner has issued a new grounds of rejection. The Brucker et al reference is deemed to show a braided electrode having a constant diameter (Figure 16). The Collins reference, in particular Figure 20B, is deemed to provide a teaching and motivation to provide a braided electrode having inner and outer layers sandwiching the braided electrode, and Levin provides the motivation to provide the electrode with a raised surface to better contact tissue.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3739

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
April 29, 2010